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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,657	05/29/2007	**Hans Grundei**	F0506-1US (E 2452 US)	1641

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EXAMINER	
MONTANO, MELISSA ANN	
ART UNIT	**PAPER NUMBER**
4166	

MAIL DATE	DELIVERY MODE
06/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,657	GRUNDEI, HANS	
	Examiner	Art Unit	
	MELISSA MONTANO	4166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/27/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Fig. 1. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: Page 3, paragraph 12, line 1 of the specification recites "that" which appears to be a misspelling of the word "than".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Reference to Claim 1

The phrase in line 5 "which may be coupled thereto" is unclear as it does not inform one having ordinary skill in the art whether the spacer must be coupled to one of either the implant or the extracorporeal coupling device, or both in order to satisfy the recitation in claim 1. Examiner interprets the language to mean that the spacer is not required to be coupled to the implant or the extracorporeal coupling device.

In Reference to Claim 14

The phrase "which shoulder is formed on the coupling element (6) of the extracorporal coupling device (4)" is unclear as it does not inform one having ordinary skill in the art whether the shoulder must be located on the coupling element (6) or the unlabeled coupling element depicted in fig. 1 below the shoulder (10) in order to satisfy the recitation in claim 14. Examiner interprets the language, as best understood, to mean that the shoulder is located on the unlabeled coupling element depicted in fig. 1 below the shoulder (10). Claim 14 is also unclear for being dependent on claim 1, which is unclear for reasons stated above.

In Reference to Claim 2-13

Claims 2-13 are dependent on claim 1 which is unclear as indicated above. Therefore, claims 2-13 include all the limitations recited in claim 1 and are unclear for the reasons stated above in reference to claim 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, and 5 are rejected under 35 U.S.C. 102(b.) as being anticipated by US Patent Application Publication 2004/0068324 A1 to Grundei (Grundei). Grundei teaches:

In Reference to Claim 1

A subcutaneous, intramuscular mounting for a rigid transcutaneous implant (2) which may be fixed intracorporally in a bone stump (11), comprising a spacer (3 and 5) between the implant and an extracorporal coupling device (4) which may be coupled thereto (page 1, paragraph 1, lines 6-11), whereby the spacer is embodied as a rigid bush (15) with a coupling element (exterior of cone 15), sealed in the intracorporal direction (it is sealed to the extent that applicant's is), to which the extracorporal coupling device may be coupled (page 1, paragraph 5, lines 52-57), wherein,

the bush widens out significantly from the end thereof facing the extracorporal direction to the end thereof facing the intracorporal direction (cone 15 widens in the intracorporeal direction) and comprises a smooth surface (cone 15 surface is smooth, see fig. 4).

In Reference to Claim 3

A mounting according to claim 1 (see rejection of claim 1 above), wherein the surface (outer wall of bush portion 5) of the bush (3 and 5) has an antibacterial effect (page 3, paragraph 34, lines 33-35).

In Reference to Claim 5

A mounting according to claim 3 (see rejection of claim 3 above), wherein the surface of the bush is plated with titanium (3 and 5 is covered with metallic wool, which is considered "plated"; page 3, paragraph 34, lines 33-35). Examiner interprets the claim to mean that at least the surface of the bush is plated, i.e. covered, with titanium (Fig. 4, reference number 8).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grundei.

In Reference to Claim 2

Grundei teaches the mounting according to claim 1 (see rejection of claim 1 above), Grundei however fails to teach wherein the length of the base edge of the bush at its extracorporally oriented end as a ratio to the length at its intracorporally oriented end as between 1:1.2 and 1:2. Applicant does not specify the criticality of the ratio recited in claim 2. The ratio could be determined through routine experimentation to obtain the desired coupling strength and ease of connection. See MPEP § 2144.04.

8. Claims 4, 6, 7, 8, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grundei in view of US Patent No. 4,615,705 to Scales et al. (Scales).

In Reference to Claim 4

Grundei teaches the mounting according to claim 1 (see rejection of claim 1 above), Grundei however fails to teach wherein the surface of the bush is plated with silver.

Scales teaches it is known that silver can be used for surgical implants in order to provide a localized antimicrobial effect (Scales col. 1, lines 42-43 and 62-64; abstract).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used silver for plating the surface of the bush, or any type of surgical implant, in order to produce an antimicrobial effect, as taught by Scales.

In Reference to Claim 6

Grundei teaches the mounting according to claim 1 (see rejection of claim 1 above), further including an adaptation tube (4) which reaches into the inside of the bush (reaches within portion 5 of bush), is seated in an interference fit (by cone 15), and is removable to which adaptation tube the coupling device can be coupled (fig. 1, reference numbers 3, 4, and 5), Grundei however fails to teach which adaptation tube has an antibacterial effect, at least on its outer wall.

Scales teaches it is known that silver can be used for surgical implants in order to provide a localized antimicrobial effect (Scales col. 1, lines 42-43 and 62-64; abstract).

It would have been obvious to one having ordinary skill in the art at the time of the invention to create an antibacterial effect by constructing or plating the surface of the adaptation tube, or any component of the implant, with silver, as taught by Scales.

In Reference to Claims 7 and 8

Grundei teaches the mounting according to claim 6 (see rejection of claim 6 above), Grundei, when modified by Scales as discussed above, teaches wherein the adaptation tube is constructed out of silver, or whose outer wall is plated with silver (Scales col. 1, lines 42-43 and 62-64; abstract).

In Reference to Claim 14

Grundei teaches the mounting according to claim 6 (see rejection of claim 6 above), further including wherein the adaptation tube (4) comprises such a length, that it is situated with its distal front edge on a shoulder (fig. 1, base seen to be located on shoulder), which shoulder is formed on the coupling element of the extracorporal coupling device, which is coupled thereto (fig. 1, depicted below reference number 18).

9. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grundei in view of Scales as applied to claim 6 above, and further in view of US Patent Application Publication No. 2003/0171825 A1 to Blunn et al. (Blunn).

In Reference to Claims 9 and 10

Grundei in view of Scales teaches the mounting according to claim 6 (see rejection of claim 6 above), Grundei in view of Scales however fails to teach wherein the adaptation tube is constructed out of a material, whose outer wall is coated with hydroxylapatite (also called hydroxyapatite) or calcium phosphate.

Blunn teaches it is known that hydroxyapatite or calcium phosphate can be used to prevent infection between the skin and prosthesis and encourages osseous integration (Blunn page 1, paragraphs 11 and 12).

It would have been obvious to one having ordinary skill in the art at the time of

the invention to have used hydroxyapatite or calcium phosphate for coating the outer wall of the adaptation tube, in the region of tissue contact, in order to prevent infection between the skin and the prosthesis and encourage osseous integration, as explicitly taught by Blunn.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grundei in view of Scales as applied to claim 6 above, and further in view of US Patent No. 5,888,215 to Roos et al. (Roos).

In Reference to Claim 11

Grundei in view of Scales teaches the mounting according to claim 6 (see rejection of claim 6 above), Grundei in view of Scales however fails to teach wherein the adaptation tube is constructed out of a material, whose outer wall is coated with titanium.

Roos teaches it is known that titanium can be used in prostheses because it quickly oxidizes which yields a barrier function against chronical tissue inflammation and becomes incorporated in the cells of the surrounding tissues (Roos col. 5, lines 61-66).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used titanium for the construction of the adaptation tube, in the region of tissue contact, in order to yield a barrier function against chronical tissue inflammation and incorporate the cells of the surrounding tissues, as explicitly taught by Roos.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grundei in view of Scales as applied to claim 6 above, and further in view of Cementless Titanium Tapered-Wedge Femoral Stem by Marshall et al. (Marshall).

In Reference to Claim 12

Grundei in view of Scales teaches the mounting according to claim 6 (see rejection of claim 6 above), Grundei in view of Scales however fails to teach wherein the adaptation tube is constructed out of a material, whose outer wall is coated with plasma titanium spray.

Marshall teaches it is known that plasma titanium spray can be used to contribute to long-term bone, i.e. tissues, in-growth (Marshall page 547, 3rd full paragraph, lines 1-3 and page 549, 1st full paragraph, lines 10-15).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used titanium plasma spray for coating the outer wall of the adaptation tube, in the region of tissue contact, in order to contribute to long-term tissue growth, as implicitly taught by Marshall.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grundei in view of Scales as applied to claim 6 above, and further in view of WO 99/64491 to Spaans et al, (Spaans).

In Reference to Claim 13

Grundei in view of Scales teaches the mounting according to claim 6 (see rejection of claim 6 above), Grundei in view of Scales however fails to teach wherein the adaptation tube is constructed out of polyurethane.

Spaans teaches it is known that polyurethane is a biomedical material that can be processed into porous shaped bodies, e.g. as implants, and have good mechanical properties (Spaans page 1, lines 15-20 and claim 20).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used polyurethane for the construction of the adaptation tube because it is a biomedical material that can be processed into porous shaped bodies, e.g. as implants, and has good mechanical properties, as taught by Spaans. Further, it has been held that the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination. See MPEP § 2144.07.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference Grundei (US Patent No. 6,485,522 B1) discloses an adapter sheath/sleeve that appears to be situated on a shoulder of the extracorporal coupling device.

The reference Grunei (US Patent No. 6,451,061 B1) discloses a leg prosthesis for adaptation to the stump of the upper leg, which includes a coupling element connected to the distal side of the prosthetic lower leg.

The reference Shorter et al. (US Patent No. 6,083,265) discloses a lower limb prosthesis with a connector, depicted in fig. 1A, which appears to widen from the extracorporeal end to the intracorporeal end.

The reference Grundei (EP Patent No. 0997118 B1) discloses a leg prosthesis with a coupling mechanism, depicted in fig. 1, that appears to widen from the extracorporeal end to the intracorporeal end.

The reference Grundei (DE Patent No. 19931882) discloses a transcutaneous bearing including an incorporeal coupling sleeve connected to an intermediate piece, which can be implanted without complications due to Sepsis.

The reference Grundei (EP Patent No. 1378215) discloses a transcutaneous coupling including a cap sleeve, an intermediate element, and a clamping sleeve surrounded by metal wool.

The reference Grundei (US Patent No. 6,869,450) discloses a transcutaneous implant including an intermediate piece, extracorporeal coupling device, rigid bushing, and flexible tube to which metallic wool is applied.

The reference Vercaigne et al. (Histomorphometrical and mechanical evaluation of titanium plasma-spray-coated implants placed in the cortical bone of goats) discloses coatings of titanium plasma-spray applied to beam-shaped implants.

The reference Shibata et al. (Antibacterial Titanium Plate Anodized by being Discharged in NaCl Solution Exhibits Cell Compatibility) discloses titanium as being widely used in biomaterials fields and applied to dental implants because of its excellent corrosion-resistance and biocompatibility.

The reference Abdullin et al. (Bactericidal and Biologically Tolerant Coatings for Medical Implants and Instruments) discloses the use of hydroxyapatite coatings of metal implants.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA MONTANO whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kenneth Bomberg can be reached on (571)272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M.M.
/Kenneth Bomberg/

Supervisory Patent Examiner, Art Unit 4124